

Application Number 10/825,955  
Amendment response to Office Action mailed July 20, 2006

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**REMARKS**

This Amendment is responsive to the Office Action dated July 20, 2006. Applicant has amended claims 1, 8, 9, 17, 19 and 20.

**Pending and Withdrawn Claims**

In the previous Response, Applicant provisionally elected Group I, Species B, and Species BB. Applicant erroneously indicated that claims 12, 14 and 15 did not read on Species B, and were thus withdrawn from further consideration. However, claims 12, 14 and 15 do read on species B, because they do not recite limitations specific to non-elected species A, C and D.<sup>1</sup> Accordingly Applicant respectfully submits that claims 1-6, 8, 9, 11, 12 and 14-27 read on the combination of Group I, Species B, and Species BB.

Furthermore, in the previous response, Applicant indicated that claims 17-20 were readable on species B. The Office Action indicated that claims 17-20 were nonetheless withdrawn because they depended from claim 15, which was withdrawn. As discussed above, Applicant erroneously indicated that claim 15 was not readable on elected species B. Therefore, claim 15 should not be withdrawn. Moreover, Applicant has amended claims 17, 19 and 20 to depend from independent claim 1, rather than claim 15. Therefore, claims 17-20 no longer depend from claim 15, and should no longer be considered withdrawn.

In sum, Applicant respectfully submits that claims 1-15, 17-42 and 44-68 are pending, with claims 7, 10, 13, 28-42 and 44-68 being withdrawn. In other words, Applicant respectfully submits that claims 1-6, 8, 9, 11, 12 and 14-27 should be examined. Applicant apologizes for any inconvenience due to the erroneous indication that claims 12, 14 and 15 did not read on Species B.

**Information Disclosure Statement**

The Office Action indicated that the reference, Michael T. Smith et al., "How do sleep disturbance and chronic pain inter-relate? Insights from the longitudinal and cognitive-behavioral clinical trials literature", Sleep Medicines Reviews, YSMRV 286-19/6/2003, from the Information Disclosure Statement filed April 5, 2005, was not considered due to poor quality and

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<sup>1</sup> See MPEP § 806.04(e) and (f).

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illegibility of the submitted copy. Applicant is seeking a cleaner copy of the reference, and will resubmit the reference as soon as one is found.

### **Claim Objections**

The Office Action stated that there appeared to be insufficient antecedent basis for the limitation "the sleep quality metric" in claim 11. Claim 11 depends from claim 1. As previously presented, claim 1 recited, "determining values of at least one metric that is indicative of sleep quality." Applicant has amended claim 1, for purposes of clarification, to recite, "determining values of at least one sleep quality metric that is indicative of sleep quality." Applicant submits that claim 1, as amended, provides sufficient antecedent basis for the limitation "the sleep quality metric" in claim 11. Accordingly, Applicant requests withdrawal of the objection to claim 11.

The Office Action also stated that there appeared to be insufficient antecedent basis for the limitation "the medical device" in claim 22. Claim 22 depends upon claim 1. In line 2, claim 1 recites "monitoring a plurality of physiological parameters of a patient via a medical device" in line 2. Thus, Applicant respectfully submits that there was sufficient antecedent basis for the limitation "the medical device" in claim 22 as originally filed, Applicant requests withdrawal of the objection to claim 22.

### **Claim Rejection Under 35 U.S.C. § 102**

The Office Action rejected claims 1-6, 8, 9, 11, and 21-27 under 35 U.S.C. § 102(b) as being anticipated by Park et al. (US 6,351,672, herein referred to as Park). Applicant respectfully traverses the rejection. Park fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Park fails to disclose or suggest determining when the patient is attempting to sleep, as recited by independent claim 1. The Office Action characterized Park's FIG. 5 as teaching this requirement. However, Park's FIG. 5 is merely a flow chart that illustrates how to monitor a patient's activity level and the variance of the activity level to determine when a patient transitions from a prolonged resting state to an active state. Specifically, Park is

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interested in determining when orthostatic compensation therapy is needed to respond to a patient standing up after a prolonged resting period.

First, Park compares the patient's activity level to an activity threshold to determine if the patient is active or inactive.<sup>2</sup> If the patient is determined to be inactive, the variance in the activity level is compared to a variance threshold to determine if the patient is resting or simply inactive.<sup>3</sup> When a patient transitions from a prolonged resting state, such as a prolonged sitting, lying down, or standing position, to an active state an increased pacing rate is delivered to provide orthostatic compensation therapy to the patient.<sup>4</sup>

Park does not disclose or suggest determining when a patient is attempting to sleep. Park is not at all concerned with whether or not the patient is attempting to sleep. Instead, Park is limited to determining whether the patient is resting, and concerned with identifying the time at which the patient transitions to an active state to determine when to deliver orthostatic compensation therapy.

Moreover, Park fails to disclose or suggest determining values of at least one sleep quality metric that is indicative of sleep quality based on at least one of the physiological parameters and a determination that the patient is attempting to sleep, as further required independent claim 1, as amended. Since Park does not disclose or suggest determining when a patient is attempting to sleep, Park also does not disclose or suggest determining a value of a sleep quality metric based on at least one of the physiological parameters and a determination that the patient is attempting to sleep. As discussed above, Park is only concerned with whether the patient is resting.

Further, Park does not disclose determining anything remotely related to sleep quality when the patient is resting. Instead, Park merely describes delivering a pacing at a base rate and continuing to monitor activity to determine when the patient transitions to an active state to determine when to deliver orthostatic compensation therapy. Neither of these activities even suggests determining values of at least one sleep quality metric that is indicative of sleep quality, as required by independent claim 1.

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<sup>2</sup> Park, figure 5, reference number 502.

<sup>3</sup> Park, figure 5, reference number 504.

<sup>4</sup> Park, abstract.

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The Office Action cited the transfer function of Park's FIG. 2 as illustrating the determination of at least one sleep quality metric. The transfer function described by Park defines a relationship between the pacing rate and activity level. More specifically, if the activity level is below the low activity threshold, pacing is set at the base rate. Additionally, the pacing rate is set at the maximum pacing rate, if the activity level is above the high activity threshold, and the pacing rate is set between the base rate and the maximum pacing rate, if the activity level is between the low and high activity thresholds.

The transfer function described by Park is in no way indicative of sleep quality or related to determining a metric indicative of sleep quality. The transfer function is used to determine a pacing rate based on a patient's activity level, and does not determine a metric indicative of sleep quality.

With respect to Applicant's claim 4, Park fails to disclose or suggest monitoring a signal from each of a plurality of orthogonally aligned accelerometers, and determining when the patient is recumbent based on a DC component of each of the signals. Park discusses U.S. Patent No. 5,354,317 to Alt, which uses a DC accelerometer to determine whether a sleep base rate or a rest base rate should be used. Park states that the DC accelerometer of Alt cannot differentiate between the patient lying on the left or right side and standing, or detect the difference between standing and sitting.<sup>5</sup> Park teaches using a single AC accelerometer, rather than a DC accelerometer, to detect patient activity over time.<sup>6</sup> Thus Park teaches away from using a DC accelerometer.

Park fails to mention a plurality orthogonally aligned accelerometers whatsoever, and instead suggests using a single AC accelerometer to detect patient activity. Thus, Park fails to disclose or suggest using more than one accelerometer, and further fails to disclose or suggest using orthogonally aligned accelerometers. For at least these reasons, Park fails to disclose or suggest monitoring a signal from each of a plurality of orthogonally aligned accelerometers, and determining when the patient is recumbent based on a DC component of each of the signals, as required by Applicant's claim 4.

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<sup>5</sup> Park, column 2, lines 41-54.

<sup>6</sup> Park, column 3, lines 17-20.

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Park also fails to disclose or suggest determining values of a sleep quality metric by identifying a first time when the patient is attempting to fall asleep, identifying a second time when the patient falls asleep based on at least one of the physiological parameters, and determining an amount of time between the first and second times, as required by Applicant's claim 11. As described previously in this Amendment, Park fails to disclose or suggest identifying when a patient is attempting to fall asleep. Instead, Park describes monitoring a patient's activity level and the variance in the activity level to determine when the patient goes from a prolonged state of rest to an active state.

In addition to failing to determine when a patient is attempting to sleep, Park also fails to disclose or suggest determining an amount of time between when the patient attempts to fall asleep and when the patient falls asleep. Col. 3, ll. 33-39 and col. 7, ll. 10-19 of Park, cited in the Office Action, are not relevant to this requirement. Instead, the cited portions are merely related to determining whether the patient is resting rather than merely inactive, such that orthostatic compensation will be provided once the patient stands. The cited portions provide no teaching relating to determining whether the patient is asleep, or determining an amount of time between when the patient attempts to fall asleep and when the patient falls asleep. For at least these reasons, Park fails to disclose or suggest all of the requirements of Applicant's claim 11.

With respect to Applicant's claim 22, Park fails to disclose or suggest associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set, for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set, and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set.

In support of the rejection of claim 22, the Examiner cited FIGS. 2 and 5 of Park's disclosure. As discussed earlier in this Amendment, Park fails to disclose or suggest determining a sleep quality metric. The transfer function of Park's FIG. 2 is in no way related to sleep quality metrics. Instead, the transfer function is used to determine a pacing rate based on a patient's activity level. The transfer function described by Park does not associate each of the determined

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sleep quality metric values and each of the determined activity levels with a current therapy parameter set. In fact, there are no determined sleep quality metric values in the Park system.

Additionally, Park's FIG. 5 does not discuss or suggest associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set. Park's FIG. 5 is a flow chart illustrating how to determine if orthostatic pacing is needed based on the activity level of a patient and the variance of the activity level. Park's FIG. 5 indicates how to determine therapy parameters based on the activity level of the patient and the variance of the activity level by first measuring an activity and variance level and then, if necessary, adjusting the pacing rate.

In contrast, Applicant's claim 22 requires that when a sleep quality metric value or an activity level is determined, the therapy parameter set that was currently used to deliver stimulation is associated with the sleep quality metric value or activity level. In this manner, sleep quality and activity metrics may be used to, evaluate the effectiveness of the therapy parameters in some embodiments according to the claim.<sup>7</sup>

Park et al. fails to disclose each and every limitation set forth in claims 1, 4, 11 and 22. Claims 2, 3, 5, 6, 8, 9, 21 and 23-27 are dependent upon claim 1, and are also in condition for allowance. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1-6, 8, 9, 11, and 21-27 under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

#### **Claim Rejection Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 26 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Park et al. in view of Cho et al. (US 6,964,641 B2, herein referred to as Cho). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Applicant traverses the rejection of claims 26 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Park in view of Cho. Claims 26 and 27 are dependent upon claim 1. Park fails to disclose or suggest the requirements of claim 1 for at least the reasons stated previously in

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<sup>7</sup> See Summary of Invention of present application.

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this Amendment. Cho lacks any teaching sufficient to overcome the basic deficiencies described above with respect to Park. Therefore, claims 26 and 27 are also in condition for allowance. Withdrawal of this rejection is requested.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 26 and 27 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

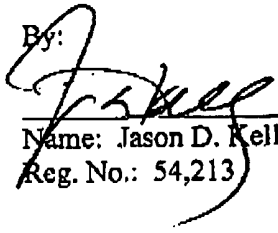
Applicant recognizes that claims 12, 14, 15 and 17-20 have not yet been examined. Applicant reserves comment regarding the applicability of the applied references to these claims at this time.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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